

Influence of the distribution of bone cement along the fracture line on the curative effect of vertebral augmentation

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Abstract

Objective: The present study was performed to evaluate the effect of different bone cement distributions along the fracture line on clinical and imaging outcomes of vertebral augmentation.

Methods: In total, 84 patients who underwent vertebral augmentation for a single osteoporotic vertebral compression fracture from January 2016 to August 2018 were retrospectively reviewed. These patients were divided into two groups according to the relationship between the bone cement distribution and the fracture line: the unilateral group ($n = 23$) and the bilateral group ($n = 61$). Postoperative clinical and imaging parameters were compared between the two groups.

Results: Statistical analyses showed no significant difference in postoperative pain relief, bone cement leakage, nerve injury, or new vertebral fracture between the two groups. Significant recovery from vertebral compression was observed in the bilateral group after surgery, but there was no significant difference in vertebral compression after surgery in the unilateral group.

Conclusions: Pain relief was similar for different types of cement distributions along the fracture line, but a bilateral cement distribution exhibited better recovery from vertebral compression and did not increase bone cement leakage in the vertebral augmentation procedure.

Keywords

Osteoporotic vertebral compression fracture, vertebral augmentation, bone cement distribution, pain relief, vertebral compression, bone cement leakage

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Introduction

Osteoporotic vertebral compression fractures (OVCFs) are very common in patients of advanced age.^{1,2} More than 3 million osteoporotic fractures will occur in the United States by 2025, and vertebral compression fractures will account for one-quarter of these osteoporotic fractures.³ Affected patients exhibit obvious spinal pain that seriously affects their quality of life.⁴ The disadvantage of conservative treatment for OVCFs is slow recovery from pain.⁵⁻⁷ Surgical treatments include percutaneous vertebroplasty (PVP) and percutaneous kyphoplasty (PKP).⁸⁻¹⁰ The bone cement distribution in vertebral augmentation is related to the treatment effect,¹¹⁻¹³ but the influence of the type of distribution of bone cement along the fracture line on the curative effect is rarely reported. Therefore, the present study focused on the effects of different types of bone cement distribution along the fracture line on pain relief, bone cement leakage, recovery from vertebral compression, and other parameters in patients with OVCFs.

Patients and methods

The ethics committee of Beijing Tsinghua Changgung Hospital approved this retrospective study, and the need for informed consent was waived because of its retrospective nature. Patients who visited our hospital from January 2016 to August 2018 were reviewed. All enrolled patients were diagnosed with an OVCF and treated by PVP or PKP. These patients had complete medical records, preoperative X-ray findings, preoperative computed tomography (CT) or magnetic resonance imaging (MRI) findings, and postoperative X-ray findings. If preoperative CT or MRI suggested rupture of the posterior wall of the fractured vertebral body, we chose PKP and aimed to minimize spinal canal leakage

of bone cement and nerve injury.^{14,15} In other cases, we chose PVP. All patients were treated with the same type of bone cement (Mendec Spine; Tecres, Verona, Italy).

The location of the vertebral fracture line was determined based on preoperative CT or MRI. The fracture line on CT had a low-density shadow due to cortical and trabecular bone fracture. The fracture line had a low-intensity signal compared with the bone marrow on the T1-weighted image, T2-weighted image, and fat-suppressed T2-weighted image. Signal changes associated with hemorrhage and edema could be seen around the fracture line and were characterized by a low-intensity signal on the T1-weighted image, mixed-intensity signal on the T2-weighted image, and high-intensity signal on the fat-suppressed T2-weighted image. The patients were divided into two groups according to the distribution pattern of bone cement on the postoperative lateral X-ray. Patients with bone cement that was primarily located on one side of the fracture line (above or below) were assigned to the unilateral group (Figure 1). Patients with bone cement that was located on both sides of the fracture line (above and below) were assigned to the bilateral group (Figure 2). Only patients with a single vertebral fracture were included in this study to more accurately analyze the treatment effect. Patients with a pathological fracture caused by a malignant tumor and those with incomplete clinical data or unclear imaging data were excluded.

The following demographic and surgical characteristics were recorded: age, sex, body mass index, compression fracture location, PVP or PKP, unilateral or bilateral puncture, bone cement dose, follow-up time, and the presence of intravertebral clefts that may influence the treatment effect.¹⁶⁻¹⁹



Figure 1. Example of a unilateral cement distribution. These images show the low-intensity-signal fracture line (arrow) of L1 and the surrounding signal changes (arrowhead) on the (a) preoperative T1-weighted image, (b) T2-weighted image, and (c) fat-suppressed T2-weighted image. (d) Bone cement was primarily located below the fracture line (bold line drawn based on preoperative magnetic resonance imaging) on the postoperative lateral X-ray. (e) The cement distribution on the posteroanterior postoperative X-ray

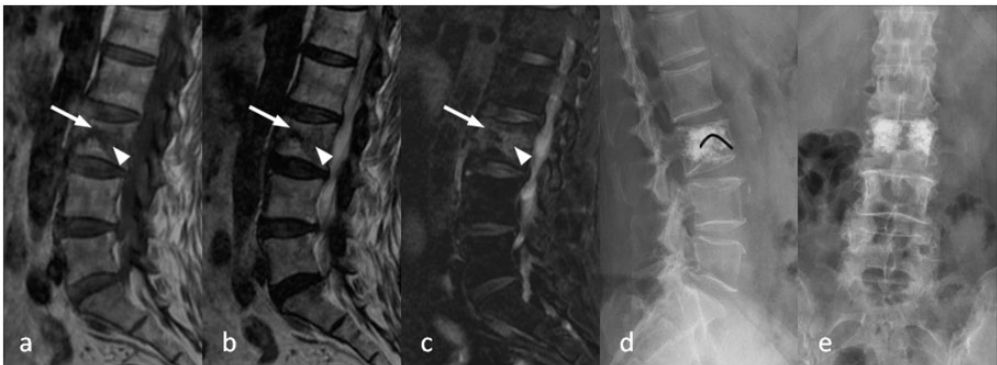


Figure 2. Example of a bilateral cement distribution. These images show the low-intensity-signal fracture line (arrow) of L3 and the surrounding signal changes (arrowhead) on the (a) preoperative T1-weighted image, (b) T2-weighted image, and (c) fat-suppressed T2-weighted image. (d) The bone cement was present above and below the fracture line (bold line drawn based on preoperative magnetic resonance imaging) on the postoperative lateral X-ray. (e) The cement distribution on the postoperative posteroanterior X-ray

Clinical evaluation

Each patient’s pain level was assessed using a visual analog scale (VAS) before the procedure, 24 hours after the procedure, 6 months after the procedure, and at the final follow-up. The pain relief rate was calculated as (preoperative VAS score–postoperative VAS score)/preoperative VAS score. Medical records were checked

to identify nerve injury after the procedure. Telephone interviews were performed to gather information about new vertebral fractures.

Imaging evaluation

Vertebral compression was defined as the ratio of the vertebral anterior margin height to the vertebral posterior margin

height on a lateral X-ray. Vertebral compression was compared before and after the procedure. Postoperative X-rays were examined for bone cement leakage, including venous leakage, fracture line leakage, intervertebral disc leakage, and spinal canal leakage.

Statistical analysis

IBM SPSS version 23 (IBM Corp., Armonk, NY, USA) was used for the statistical analyses. Categorical variables between the two groups were analyzed using the chi-squared test. If the conditions of the chi-squared test were not met, Fisher's exact test was used for the statistical analysis. Changes in vertebral compression and VAS scores before and after surgery in the same group were analyzed using paired t tests. Other numerical variables were analyzed using Student's t test. The level of statistical significance was defined as a P value of <0.050.

Results

Eighty-four patients were included in this study. The patients comprised 12 men and

72 women with an average age of 73.31 years. L1 was the most common fracture site, followed by T12. All patients were followed up. The average follow-up time was 19.35 months (range, 6–36 months). Twenty-three patients were assigned to the unilateral group, and 61 patients were assigned to the bilateral group. There were no differences in baseline demographic or surgical characteristics between the two groups (Table 1).

The clinical results are listed in Table 2. At 24 hours after the procedure, the mean VAS score had decreased from 7.52 to 2.09 in the unilateral group ($P = 0.000$) and from 7.49 to 1.43 in the bilateral group ($P = 0.000$). There was no significant difference in the pain relief rate at 24 hours, 6 months after the procedure, or the final follow-up between the two groups. Additionally, no significant differences were found in nerve injury or new vertebral fracture during follow-up. The overall clinical results among all 84 patients are also shown in Table 2.

The imaging results are listed in Table 3. Vertebral compression increased from 69.62% to 75.49% in the bilateral group

Table 1. Demographic and surgical characteristics

Characteristics	Overall (n = 84)	Unilateral distribution group (n = 23)	Bilateral distribution group (n = 61)	P
Age, years	73.31 ± 9.36	74.13 ± 7.95	73.00 ± 9.89	0.625
Female	72 (85.7)	20 (87.0)	52 (85.2)	1.000
Body mass index, kg/m ²	23.96 ± 3.96	24.66 ± 4.36	23.70 ± 3.80	0.324
Fracture location				0.311
Upper thoracic	18 (21.4)	6 (26.1)	12 (19.7)	
T12	22 (26.2)	4 (17.4)	18 (29.5)	
L1	30 (35.7)	11 (47.8)	19 (31.1)	
Lower lumbar	14 (16.7)	2 (8.7)	12 (19.7)	
Cleft	21 (25.0)	4 (17.4)	17 (27.9)	0.323
Percutaneous kyphoplasty	7 (8.3)	2 (8.7)	5 (8.2)	1.000
Bone cement volume, mL	4.14 ± 0.89	3.97 ± 0.92	4.20 ± 0.88	0.295
Unilateral puncture	14 (16.7)	6 (26.1)	8 (13.1)	0.192
Follow-up duration, months	19.35 ± 7.32	20.61 ± 7.37	18.87 ± 7.31	0.334

Data are presented as mean ± standard deviation or n (%).

Table 2. Clinical outcomes

	Overall (n = 84)	Unilateral distribution group (n = 23)	Bilateral distribution group (n = 61)	P
VAS score				
Before the procedure	7.50 ± 2.04	7.52 ± 2.17	7.49 ± 2.01	0.953
24 hours after the procedure	1.61 ± 1.87	2.09 ± 2.21	1.43 ± 1.71	0.205
P (before to 24 hours after)	0.000	0.000	0.000	
6 months after the procedure	0.70 ± 1.32	0.44 ± 0.90	0.80 ± 1.45	0.168
Follow-up	0.63 ± 1.30	0.48 ± 0.95	0.69 ± 1.41	0.511
Pain relief rate, %				
24 hours after the procedure	79.64 ± 22.99	74.75 ± 24.74	81.48 ± 22.23	0.234
6 months after the procedure	90.83 ± 17.67	94.64 ± 11.18	89.39 ± 19.45	0.129
Follow-up	91.75 ± 17.48	94.33 ± 11.48	90.78 ± 19.26	0.409
Nerve injury	1 (1.2)	0 (0.0)	1 (1.6)	1.000
New vertebral fracture	2 (2.4)	0 (0.0)	2 (3.3)	1.000

Data are presented as mean ± standard deviation or n (%).
VAS, visual analog scale

Table 3. Radiographic outcomes

	Overall (n = 84)	Unilateral distribution group (n = 23)	Bilateral distribution group (n = 61)	P
Vertebral compression				
Before the procedure, %	70.89 ± 15.08	74.24 ± 16.37	69.62 ± 14.51	0.213
After the procedure, %	75.07 ± 13.18	73.95 ± 12.16	75.49 ± 13.62	0.636
P (after to before)	0.001	0.910	0.000	
Bone cement leakage				
Venous	39 (46.4)	11 (47.8)	28 (45.9)	0.875
Fracture line	31 (36.9)	12 (52.1)	19 (31.1)	0.075
Intervertebral disc	6 (7.1)	0 (0.0)	6 (9.8)	0.182
Spinal canal	14 (16.7)	5 (21.7)	9 (14.8)	0.515

Data are presented as mean ± standard deviation or n (%).

after the procedure, and this difference was statistically significant (P = 0.000). Vertebral compression did not differ significantly in the unilateral group after the procedure. There were no significant differences in venous cement leakage, fracture line cement leakage, intervertebral disc leakage, or spinal canal leakage between the two groups. The overall imaging results among all 84 patients are also shown in Table 3.

Discussion

The present study revealed no significant difference in pain relief after the procedure between the two groups. Liang et al.²⁰ reached the same conclusion after performing their finite element analysis. The asymmetric distribution of bone cement under vertical pressure (cement located upward or downward in the vertebral body) did not significantly increase the maximum

displacement around the fractured area compared with the symmetric distribution. Therefore, an asymmetric cement distribution may also lead to pain relief after vertebral augmentation. The analgesic mechanism of vertebral augmentation is not clear.²¹ The injection of bone cement may increase the mechanical stability of the fractured vertebral body, helping to relieve pain,²² or the heat generated by bone cement polymerization may cause thermal necrosis of the nerve tissue in the vertebral body and thus relieve pain.²³⁻²⁵ The second hypothesis may explain the findings in the present study because there was no significant association between pain relief and the distribution of bone cement along the fracture line during vertebral augmentation.

The present study showed that the unilateral distribution of bone cement along the fracture line was not conducive to the recovery of vertebral height after vertebral augmentation. A case-control study by Zhang et al.²⁶ showed that patients with a bone cement distribution around the upper and lower endplates had a significantly lower incidence of recompression than patients with other patterns of cement distribution (e.g., below the upper endplate or above the lower endplate). The finite element analysis performed by Liang et al.²⁰ also showed that an asymmetrical cement distribution around the fractured area was more likely to induce recollapse of the augmented vertebral body because the maximum von Mises stress in the cancellous and cortical bone of the augmented vertebral body was significantly higher in the asymmetrical cement distribution. However, the number of new vertebral fractures in the present study (including refracture of cemented vertebrae) was small in both groups, and there was no significant difference between the two groups. This conclusion requires further confirmation in long-term follow-up or prospective studies.

Intervertebral disc leakage of bone cement is a risk factor for new symptomatic vertebral compression fractures after PVP or PKP.²⁷⁻³⁰ Bone cement spinal canal leakage may cause nerve compression and requires surgical intervention.³¹ The present study showed no significant difference in bone cement leakage between the two groups; likewise, He et al.³² demonstrated that the bone cement distribution was not a risk factor for bone cement leakage. Therefore, a bone cement distribution on both sides of the fracture line does not increase the probability of complications related to bone cement leakage compared with a unilateral distribution.

Previous studies have shown that PVP and PKP offer similar pain relief and that PKP has the advantages of less bone cement leakage, better recovery of anterior vertebral height, and reduced nerve injury and the disadvantages of a longer operation time and higher cost compared with PVP.^{14,15,33-36} To avoid the influence of PVP or PKP on the indexes observed in the present study, we compared the proportion of PKP between the two groups and found no significant difference (Table 1).

To achieve better therapeutic effects, bone cement should be widely distributed on both sides of the fracture line during vertebral augmentation. Spinal X-ray, CT, and MRI should be completed before the procedure to determine the exact position of the fracture line. A puncture needle should be placed on the fracture line as far as possible during the operation. The surgeons should always be alert to leakage of bone cement to the posterior margin of the vertebral body.

This study has several limitations. First, the absence of significant differences in pain relief and bone cement leakage may be explained by the relatively small sample size; the study population may not have been large enough to show the differences between these two groups through statistical

analysis. Second, the new vertebral fracture rates in both groups were lower than those in previous studies,^{37,38} which may have occurred because of the short follow-up time and small sample size. Third, it is not sufficiently accurate to assess bone cement leakage using postoperative X-ray alone without the use of CT, and this may have affected the final conclusion. Furthermore, no imaging data were available during the long-term follow-up to assess the changes in vertebral compression in the two groups; this requires further study.

Conclusions

The bone cement used in vertebral augmentation procedures should be distributed on both sides of the fracture line. This methodology produces better recovery from vertebral compression without increasing bone cement leakage compared with unilateral cement distribution while providing the same degree of pain relief.

Declaration of conflicting interest

The authors declare that there is no conflict of interest.

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